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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,400	07/20/2001	Lee M. Nadler	50059/007002	7028

7590 10/16/2008

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EXAMINER	
JUEDES, AMY E	
ART UNIT	PAPER NUMBER
1644	
MAIL DATE	DELIVERY MODE
10/16/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/830,400	NADLER ET AL.	
	Examiner	Art Unit	
	AMY E. JUEDES	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43,45 and 46* is/are pending in the application.

4a) Of the above claim(s) *1-17,20-43,45 and 46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18* is/are rejected.

7)☒ Claim(s) *19* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed 9/2/08 in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/2/08 has been entered.

Claim 18 has been amended.
Claims 1-43 and 45-46 are pending.

Claims 1-17, 20-43, and 45-46 stand withdrawn from further consideration pursuant to 37 CFR 1.14209 as being drawn to a nonelected invention.

Claims 18-19 are under examination.

2. In view of Applicant's amendment to the claims, the previous grounds of rejection are withdrawn. However, Applicant's arguments relevant to the new grounds of rejection will be addressed below.

3. The following are new grounds of objection and rejection.

4. Claim 19 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The test for a proper dependent claim is whether the dependent claim includes every limitation of the parent claim. A proper dependent claim shall not conceivably be infringed by anything which would not also infringe the basic claim. In the instant case claim 19 is drawn to a peptide consisting of SEQ ID NO: 1 (a 9 amino acid peptide). However, claim 18, from which it depends is drawn to a peptide 50 amino acids in length. Thus, a 9 amino acid peptide might infringe claim 19, but would not infringe claim 18, which requires a 50 amino acid peptide.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same

and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 18 is rejected under 35 U.S.C. 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

An isolated hTERT peptide "50 amino acids in length that binds to a human major histocompatibility complex class IA molecule", wherein the peptide comprises SEQ ID NO: 1.

Applicant indicates that support for the new limitation of the claim can be found on page 78 of the specification.

A review of the specification fails to reveal support for the new limitations.

At page 78, the specification discloses that candidate epitopes localize to a 50mer stretch of hTERT starting at residue 535, and that the I540 peptide (i.e. SEQ ID NO: 1) is found within this 50mer. However, the disclosure a single 50 amino acid peptide that starts at residue 535 of hTERT and comprises SEQ ID NO: 1 does not provide support for the more broad recitation of any 50 amino acid peptide comprising SEQ ID NO: 1, as now claimed. For example, the claims might encompass a peptide starting at residue 500 of hTERT and comprising SEQ ID NO: 1. The specification only discloses a single 50 amino acid peptide starting a residue 535.

7. Claim 18 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

A peptide consisting of SEQ ID NO: 1, wherein the peptide binds to a human major histocompatibility complex class I A molecule,

does not reasonably provide enablement for:

A 50 amino acid peptide that binds to a human major histocompatibility complex class I A molecule, wherein said peptide comprises SEQ ID NO: 1,

The specification disclosure is insufficient to enable one skilled in the art to practice the invention as claimed without an undue amount of experimentation. Undue experimentation must be considered in light of factors including: the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill in the art, the level of predictability of the art, the amount of direction provided by the inventor, the existence of working examples, and the quantity of experimentation needed to make or use the invention, see *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).

In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) states, "The amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art." "The "amount of guidance or direction" refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly stated in the specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling" (MPEP 2164.03). The MPEP further states that physiological activity can be considered inherently unpredictable. With these teachings in mind, an enabling disclosure, commensurate in scope with the breadth of the claimed invention, is required.

The instant claims are drawn to a genus of 50 amino acid hTERT peptides comprising SEQ ID NO: 1, wherein the peptides bind to MHC class I A molecules. It is well known that the structure of MHC class I molecules allows binding of peptides between 8 and 10 amino acids in length (see Koopmann et al. and Altuvia et al., both of record). The instant specification discloses several examples of MHC class I A binding hTERT peptides, however, all of the examples are of peptides of less than 10 amino acids. Thus, based on the state of the art and the lack of working examples provided by the instant specification, it would require undue experimentation to make and use the peptides as broadly claimed (i.e. to make and use peptides of 50 amino acids in length that bind to MHC class I A molecules).

Applicant's arguments filed 9/2/08 have been fully considered, but they are not persuasive.

Applicant argues that those skilled in the art would recognize that peptides longer than 8 to 10 amino acids can bind to MHC class I, as evidenced by Stryhn et al., 2000.

Stryhn et al. teach that certain peptides longer than 8-10 amino acids can be accommodated in MHC class I by a protrusion mechanism. However Stryhn et al. only examine peptides of up to 18 amino acids in length. Stryhn et al. do not provide any evidence that peptides as long as 50 amino acids (as is encompassed by the instant claims) can bind to MHC class I. Furthermore, Stryhn et al. demonstrate that the ability of longer peptides to bind to MHC class I is highly unpredictable. For example, certain peptides increased to 16-18 amino acids in length showed only a 10 fold reduction in binding, while other peptides extended to comprise only 11 amino acids show up to a 100,000 fold loss in binding (see page 3091 in particular). Thus, the ability of longer peptides, particularly, those up to 50 amino acids in length, to bind to MHC class I is extremely unpredictable, and the instant specification does not provide any guidance or examples of hTERT peptides longer than 10 amino acids that can bind to MHC class I.

8. No claim is allowed. Claim 19 is free of the prior art, and would be allowable if written in independent form.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E. Juedes, Ph.D. whose telephone number is 571-272-4471. The examiner can normally be reached on 6am - 2pm, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status

information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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